IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Appl. No. | : | 10/692,083 | Confirmation No.: | 8282 |
| Applicant | : | William Martin Belef | | |
| Filing Date | : | October 22, 2003 | | |
| Title | : | Methods for Treating Spinal Discs | | |
| Group Art Unit | : | 3738 | | |
| Examiner | : | Suba Ganesan | | |
| Docket No. | : | 15457.4016 | | |
| Customer No. | : | 34313 | | |

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**SUPPLEMENTAL APPEAL BRIEF AND REQUEST FOR ORAL HEARING**

Sir:

***Real Party in Interest***

Gateway Medical, Inc. Inc. is the real party in interest.

***Related Appeals and Interferences***

There are no related appeals of interferences.

***Status of Claims***

Claims 1-33 are pending in this application and all of these claims stand rejected.

Claims 1-33 are on appeal.

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CERTIFICATE OF MAILING
37 CFR §1.8

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Dated: November 26, 2007

Lynne Fulmer

OHS West:260341571.1

***Status of Amendments***

All amendments which have been filed have been entered.

***Summary of Claimed Subject Matter***

There are three independent claims, which are claims 1, 15 and 27. These claims are directed to a method comprising, as recited in claim 1, creating an opening in the annulus fibrosis of a spinal disc, performing a procedure within the interior of the disc and applying energy to the tissue surrounding the opening to substantially close the opening. Claim 15 also includes the steps of removing at least a portion of the nucleus pulposus to create a space within the annulus fibrosis, lining the space with a liner and filling the space with a fill material. Claim 27 adds to claim 15 the limitation of using some of he nucleus pulposus removed from the disc as fill material. Claims 1-33 are summarized below with references to the drawings shown in the parentheses.

Claim 1 reads as follows:

> "1. A method for closing an opening extending through annulus fibrosis into an interior of a spinal disc, the method comprising:
> creating an opening through the annulus fibrosis into the interior of the disc;
> performing a procedure within the interior of the disc; and
> applying energy to tissue surrounding the opening to substantially close the opening."

This method is illustrated, for example, in Figs. 2A-2I and 8A-8C. As described in paragraphs 58 and 93, the opening 95 is created in the annulus fibrosis 92 and opening 95 communicates with the interior region 93 which contains the nucleus pulposus. As disclosed in paragraphs 65 and 94, a procedure may then be performed, e.g., by introducing one or more therapeutic agents through opening 95 into the interior region 93. As disclosed in paragraphs 70 and

96, energy may then be applied to the annulus fibrosis tissue surrounding the passage to close the passage.

The step of removing the nucleus pulposus recited in claim 2 is disclosed in paragraphs 58 and 59 and the step of introducing an implant as recited in claim 3 is disclosed at paragraph 85. Claim 4 recites introducing a therapeutic agent which is disclosed in paragraphs 65, 94 and 95.

Claim 5 recites introducing the therapeutic agent with a needle which is described in paragraph 106 and illustrated in Figs. 10A-10C. Claim 13 recites that the needle is provided with a syringe which is disclosed in paragraph 106 and the step of disconnecting the syringe after introducing the therapeutic agent as recited in claim 14 is described in paragraph 106 as well. The step of applying RF energy is described in paragraphs 109 and 55.

The step of introducing an elongate member, e.g., a needle, into the interior of a disc as recited in claim 6 is described in paragraph 106. The step of disposing an energy element on the distal portion of the elongate member as described in claim 7 is disclosed in paragraph 109. The step of activating the energy element recited in claim 7 and the step of withdrawing the elongate member while the energy element is activated recited in claim 8 are each described in paragraph 109. The step of introducing a therapeutic agent through a needle is described in paragraph 106. The step of inserting an energy element into the lumen of a needle until it extends beyond the distal end of the needle and of delivering electrical energy via the element as recited in claim 10 is disclosed in paragraph 109.

The steps of connecting handle to a needle as recited in claim 11 and that the needle is electrically conductive as recited in claim 12 are disclosed in paragraph 107.

Claim 15 recites creating an opening in the annulus fibrosis of a disc and removing nucleus pulposus from the disc as disclosed in paragraphs 58 and 59, lining the space created by such removal with a nonporous-bioabsorbable liner as described in paragraph 60, filling the space with a fill material sufficient to cause the liner to expand to substantially engage tissues surrounding the space as described in paragraph 61 and closing the opening by applying energy as disclosed in paragraph 70.

Claim 16 recites that the fill material is nucleus pulposus and claim 17 recites that it is the nucleus pulposus removed from the disc. Both features are described in paragraph 61. Claims 18, 28 and 31 recite that the fill material is an extra-cellular matrix material and claim 19 recites that this matrix material can be intestinal submucosa, stomach submucosa or bladder submucosa, all of which is described in paragraph 61. Similarly, claims 20, 28 and 33 recite that the fill is an autologous therapeutic agent which is described in paragraph 61 and claims 21 and 28 recite that the fill material can be a concentrated growth factor which is also disclosed in paragraph 61.

Claim 22 recites that the fill is an interpenetrating polymer network which is disclosed in paragraph 62. Claim 23 recites that the fill material is sufficient to cause the bladder to expand to substantially occupy the space created by removal of the nucleus pulposus which is described in paragraph 63. Claim 24 recites that the bladder comprises an extra-cellular matrix material and claim 26 recites that the liner is an extra-cellular matrix material which is disclosed in paragraph 49. Claim 25 recites that the bladder is one of intestinal submucosa, stomach submucosa or bladder submucosa which are described in paragraph 49.

Claim 27 recites the steps of creating an opening in the annulus fibrosis and removing nucleus pulposus which is described in paragraphs 58 and 59, lining the space thereby created with a

substantially non-porous liner which is described in paragraph 60, filling the space to expand the liner to substantially engage the tissue surrounding the space which is described in paragraph 61, using nucleus pulposus from the disc as the fill material which is described in paragraph 61 and closing the opening with energy which is described in paragraph 70. Claim 30 recites introducing fill material into the space created by removal of the nucleus pulposus before introducing the lining which is described in paragraph 65 and claim 32 recites that such fill material comprises a slurry comprising saline, an antibiotic, a steroid or a non-steroidal anti-inflammatory drug which is disclosed in paragraph 65.

***Grounds of Rejection To Be Reviewed on Appeal***

Claims 1-12 have been rejected as anticipated by Lambrecht Patent No. 6,482,235.

Claims 13 and 14 have been rejected as unpatentable over Lambrecht in view of Underwood Patent No. 6,929,640.

Claims 15-18, 20, 23 and 27-29 have been rejected as unpatentable over Froning Patent No. 3,875,595 in view of Lambrecht.

Claims 19 and 24-26 have been rejected as unpatentable over Froning in view of Lambrecht and Carr Patent No. 5,733,337.

Claim 22 has been rejected as unpatentable over Froning in view of Lambrecht and Felt Patent No. 6,140,452.

Claims 30-33 have been rejected as unpatentable over Froning in view of Lambrecht and Michelson Patent No. 4,968,298.

***Argument***

Claims 1-12

The Examiner's rejection of claims 1-12 states that Lambrecht discloses "creating an opening through the annulus fibrosis into the interior of the disc." This is not true. The Examiner refers to Fig. 19 of Lambrecht as support for his position, but it is clear that the Examiner has things backwards. As shown in Fig. 16A and as disclosed at column 16, lines 56-59 of Lambrecht, the opening in the annulus fibrosis is **not** created by some outside force, but rather is a **pre-existing defect** in the annulus fibrosis which has allowed the nucleus pulposus to leak through the annulus fibrosis into space outside the disc.

Lambrecht then proposes to treat this condition by introducing a "barrier" 12 into the interior of the annulus fibrosis which barrier is to be sealed to the nucleus pulposus on the internal side of the defect and thereby block further leakage of the opening in the annulus fibrosis which, as shown in Figs. 21A, 22A, 23A, 23B, 24A, 25, 26 and 27, for example, is **never closed**. Thus, Lambrecht does not disclose either creating an opening in the annulus fibrosis nor does it disclose closing an opening in the annulus fibrosis. What it does disclose is creating an interior barrier which **blocks** the opening in the annulus fibrosis without closing it. Since Lambrecht does not close the opening in the annulus fibrosis, it is not possible that he uses energy, or anything else, to close the opening. Rather, as disclosed at column 20, lines 9-49, the purpose of the energy delivery in Lambrecht is to attach the barrier 12 to the nucleus pulposus 20 and to the inner wall of the annulus fibrosis 10. Thus, Lambrecht is far afield from the recited method and cannot be considered to anticipate or in any other way render

claims 1-12 unpatentable.

Claim 13 and 14

Claims 13 and 14 have been rejected over Lambrecht in view of Underwood, with Underwood being relied upon for its disclosure of the use of a syringe to inject a therapeutic agent. However, these references are directed to completely different procedures which are essentially the antithesis of each other. Unlike Lambrecht, which is directed to preventing the loss of nucleus pulposus material, Underwood is directed to using energy ablation to **remove** nucleus pulposus material. Underwood contains no disclosure of using energy to close an opening in the annulus fibrosis and is using energy for a totally different purpose.

In addition, Applicant can find no disclosure of the use of a syringe in Underwood, but this is beside the point. What is important is that it is not rationally possible to combine Underwood with Lambrecht. If this were done, the removal of nucleus pulposus material as taught in Underwood would undermine the use of the barrier of Lambrecht which is intended to prevent the loss of nucleus pulposus material.

Claims 15-18, 20, 23 and 27-29

The Examiner's characterization of Froning Patent No. 3,875,595 in numbered paragraph 6 of the final rejection dated May 25, 2007 is generally accurate. However, the Examiner's characterization of the Lambrecht patent is, both for the reasons stated above and additional reasons, seriously inaccurate. The Examiner recognizes that Froning does not disclose:

1. A bioabsorbable liner.

2. The use of energy to close the opening in the annulus fibrosis.

3. The use of the nucleus pulposus removed from the disc as the fill material used to fill the liner.

As discussed above, there is absolutely no disclosure of creating or closing an opening in the annulus fibrosis of a disc in Lambrecht. Lambrecht merely blocks a pre-existing opening with an internally-located barrier 12 and applies energy to adhere the barrier to the internal remaining nucleus pulposus and the inner wall of the annular fibrosis.

With regard to the use of the patient's nucleus pulposus which has been removed from the disc to fill the liner as recited in claim 16, the Examiner's characterization of Lambrecht as teaching "the use of the nucleus pulposus within a defect (column 21, line 38)", is inaccurate. This disclosure in Lambrecht simply recognizes that there is nucleus pulposus within the annular fibrosis of the disc being treated. It says absolutely nothing about removing any of that nucleus pulposus nor does it say anything about using nucleus pulposus from any source to fill a space within the annulus fibrosis, much less that of the patent. Thus, this mischaracterization of Lambrecht renders reliance upon it fatally defective.

Lambrecht does disclose the use of resorbable materials at column 11, lines 38-41, **but not** for a liner or anything comparable to a liner. Rather, this disclosure relates to **anchors** such as elements 1 and 2 shown in Figs. 2A and 2B of Lambrecht. Thus, the Examiner's rejection with regard to this element of the claims is nothing more than a patch work of teachings which can only be prompted by the disclosure and claims of the present application. As such, the rejection is erroneous and should be reversed.

With regard to claim 17, the Examiner asserts, with absolutely no support, that "it would have been obvious to one of ordinary skill in the art to use the nucleus pulposus from the same patient in order to avoid homologous reactions." This is, of course, a misuse use of the word "homologous", but Applicant speculates that the Examiner had in mind biological rejection by

reason of an immune response. However, given the fact that Froning discloses the use of a liner, which will permanently separate the fill material from the surrounding tissue, Froning would have no concern about immune response rejections and therefore contains no disclosure with regard to the biological or physiological properties of the fill material. Thus, as in the case of claim 16, the rejection of claim 17 is based on improper reconstruction of the prior art in an erroneous effort to meet the terms of claim 17.

With regard to claims 18 and 28, the Examiner's mistaken basis for rejecting claim 17 is extended by, first, erroneously adopting the premise that there is something in the prior art that discloses the use of nucleus pulposus from the same patient as fill material and then, second, recharacterizing the nucleus pulposus as "extra-cellular matrix material". As disclosed in paragraph 85, nucleus pulposus is not an extra-cellular matrix material. The rejection is erroneous because its premises are erroneous and, as will be seen, it is inconsistent with the rejection of claims 19 and 24-26.

The rejection of claim 20 falls into the same category as the rejection of claims 18 and 28. This rejection merely states the fact that nucleus pulposus from the same patient comprises an autologous material but such a statement does nothing to cure the defects in rejections of claims 17, 18 and 28 upon which the rejection of claim 20 is based.

The rejection of claim 21 which is directed to the use of a concentrated growth factor derived from centrifuged plasma of the patient, is based on the Examiner's assertion that it is the use of a "known material on the basis of its suitability". This assertion is completely unsupported. This lack of any support makes it plain that there is no sound basis for rejecting the claim. All that is offered is the arbitrary statement that such material is known to be suitable for the recited use.

Since the rejections of claims 17, 18, 20, 21 and 28 are based on no identifiable support, such rejections are based on asserted knowledge held by the Examiner. Thus, 37 CFR 1.104(d)(2), which provides that "when a rejection...is based on facts within the personal knowledge of an employee of the Office," the Applicant is entitled to request the affidavit of such an employee, is applicable here. Applicant requests an affidavit which contains support for these rejections which are apparently based on the personal knowledge of the Examiner.

Claims 19 and 24-26

These claims recite the use of an extra-cellular matrix material which can comprise at least one of intestinal submucosa, stomach submucosa or bladder submucosa and have been rejected over Froning in view of Lambrecht and Carr Patent No. 5,733,337. The Examiner has, of course, shifted gears in making this rejection as can be seen by comparing the rejection of claims 18 and 28 with the present rejection. Claims 18 and 28 were rejected on the erroneous basis that the nucleus pulposus from the patient was a "naturally occurring extra-cellular matrix material", but the Examiner in rejecting claims 19 and 24-26 relies upon Carr for its disclosure of such submucosa materials. More important than the Examiner's inconsistency is the fact that the Carr disclosure does nothing to remedy the deficiencies in the combination of Froning and Lambrecht. Furthermore, the choice of the material of Carr as a fill material is not suggested in any way in the prior art nor is there any basis in the record for concluding that it would be obvious to one of ordinary skill in the art.

Claim 22

Claim 22 has been rejected as unpatentable over Froning in view of Lambrecht and Felt Patent No. 6,140,452. Felt does disclose a filler material comprising a polymer for filling a balloon which may be used as a prosthesis. However, Felt does not cure any of the deficiencies in the

combination of Froning and Lambrecht which have previously been discussed. These deficiencies include the facts that Lambrecht does not disclose creating or closing an opening in the annulus fibrosis, much less applying energy to the tissue surrounding such an opening to close it. Thus, this rejection is in error and should be reversed.

Claims 30-33

Claims 30-33 have been rejected as unpatentable over Froning in view of Lambrecht and Michelson Patent No, 4,968,298. This combination of references is completely untenable. Claims 30-33 are directed to the disclosure which appears in paragraphs 65 and 66 of the present application and which is an alternate procedure in which some of the fill material is introduced before introduction of the liner. There is absolutely no suggestion of such a procedure in Froning or Lambrecht and the Michelson patent is far afield. The Michelson device is nothing more than a suction irrigation device for use following a conventional discectomy according to which debris is removed from the space in which the discectomy is performed. The irrigation fluid of Michelson is aspirated to remove it from the discectomy space. This is the direct antithesis of the invention of claims 30-33 in which fill material is introduced into the cavity 96 in the annulus fibrosis 92 prior to introduction of the liner 12. The irrigation fluid of Michelson, which is removed from the space in which the discectomy is performed, is the exact opposite of the recited deployment of a fill material. Thus, Michelson cannot be properly combined with Lambrecht or Froning and, even if such a combination were permissible, it would not result in the invention claimed in claims 30-33. Thus, this rejection is in error and should be reversed.

***Conclusion***

The recurring theme which defeats the attempted rejection of claims 1-33 in this application is the erroneous characterization of Lambrecht as disclosing:

1. Creating an opening in the annulus fibrosis.

2. Closing an opening in the annulus fibrosis.

3. Using energy applied to the tissue surrounding the opening in the annulus fibrosis to close it.

This fundamental defect is then compounded by the attempts to combine Lambrecht with other references in an effort to reconstruct the invention recited in the appealed claims. These attempted combinations are fatally flawed for the reasons set forth above. Thus, it is respectfully submitted that the rejections of claims 1-33 should be reversed.

***Request for Oral Hearing***

Applicant hereby repeats his request that an Oral Hearing be scheduled in this application.

***Fees***

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

Orrick, Herrington & Sutcliffe, LLP

Dated: November 26, 2007

By: _____
James W. Geriak, Reg. No. 20, 233

ORRICK, HERRINGTON & SUTCLIFFE LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614-2558
Telephone: 949/567-6700
Facsimile: 949/567-6710

## *APPENDIX*

1. A method for closing an opening extending through annulus fibrosis into an interior of a spinal disc, the method comprising:

creating an opening through the annulus fibrosis into the interior of the disc;

performing a procedure within the interior of the disc; and

applying energy to tissue surrounding the opening to substantially close the opening.

2. The method of claim 1, wherein the step of performing a procedure comprises removing at least a portion of the nucleus pulposus material from the interior of the spinal disc.

3. The method of claim 1, wherein the step of performing a procedure comprises introducing an implant within the interior of the spinal disc.

4. The method of claim 1, wherein the step of performing a procedure comprises introducing a therapeutic agent into the interior of the spinal disc.

5. The method of claim 1, wherein the step of applying energy comprises applying radio frequency energy.

6. The method of claim 1, wherein the step of performing a procedure comprises introducing a distal portion of an elongate member into the interior of the disc.

7. The method of claim 6, wherein the step of applying energy comprises:

disposing an energy element on the distal portion of the elongate member within the opening; and

activating the energy element within the opening.

8. The method of claim 7, further comprising withdrawing the distal portion of the elongate member through the opening while the energy element is activated.

9. The method of claim 6, wherein the step of performing a procedure comprises:

inserting a distal end of a needle through tissue to a predetermined location within a patient's body; and

delivering a therapeutic agent through a lumen of the needle to the predetermined location.

10. The method of claim 9, wherein the step of applying energy comprises:

inserting an energy element into the lumen until an electrode on a distal tip of the energy element extends beyond the distal end of the needle; and

delivering electrical energy from a source of electrical energy via the electrode to tissue surrounding the electrode to substantially close the passage.

11. The method of claim 10, wherein the step of inserting an elongate element into the lumen comprises connecting a handle member to a proximal end of the needle, the elongate element extending from a distal end of the handle member.

12. The method of claim 11, wherein:

the needle comprises an electrically conductive material, and the elongate element comprises an electrically insulated outer surface that extends through the needle; and

the handle member comprises an electrically conductive region that is coupled to the needle when the handle member is connected to the needle, the conductive region being coupled to the source of electrical energy.

13. The method of claim 12, wherein the step of delivering a therapeutic agent comprises injecting the therapeutic agent through the lumen from a syringe connected to the proximal end of the needle.

14. The method of claim 13, further comprising disconnecting the syringe from the proximal end of the needle before connecting the handle member to the proximal end.

15. A method for treating a spinal disc of a patient, the spinal disc comprising annulus fibrosis and nucleus pulposus with an anterior region defined by the annulus fibrosis, the method comprising:

removing at least a portion of the nucleus pulposus material from the interior region to define a space, wherein the step of removing comprises creating an opening in the annulus fibrosis to access the interior region of the annulus fibrosis;

lining the space with a substantially nonporous, bioabsorbable liner material;

filling the space with a fill material sufficient to cause the liner material to expand to substantially engage tissue surrounding the space; and

closing the opening after filling the space with fill material, wherein the closing step comprises applying energy to annulus fibrosis tissue surrounding the opening.

16. The method of claim 15, wherein the fill material comprises nucleus pulposus.

17. The method of claim 16, wherein the nucleus pulposus used to fill the space comprises nucleus pulposus removed from the disc.

18. The method of claim 15, wherein the fill material comprises a naturally occurring extra-cellular matrix.

19. The method of claim 18, wherein the extra-cellular matrix material comprises at least one of intestinal submucosa, stomach submucosa, or bladder submucosa.

20. The method of claim 15, wherein the fill material comprises an autologous therapeutic agent.

21. The method of claim 15, wherein the autologous therapeutic agent comprises a concentrated growth factor derived from centrifuged plasma of the patient.

22. The method of claim 15, wherein the space is filled with a material comprising interpenetrating polymer network (IPN) material.

23. The method of claim 15, wherein the liner material comprises a substantially nonporous, bioabsorbable bladder, wherein the step of lining the space comprises introducing the bladder within the space, and wherein the step of filling the space comprises filling the bladder with a fill material sufficient to cause the bladder to expand to substantially occupy the space.

24. The method of claim 23, wherein the bladder comprises an extra-cellular matrix material.

25. The method of claim 24, wherein the extra-cellular matrix material comprises at least one of intestinal submucosa, stomach submucosa, or bladder submucosa.

26. The method of claim 15, wherein the liner material comprises a sheet of naturally occurring extra-cellular matrix material.

27. A method for treating a spinal disc of a patient, the spinal disc comprising annulus fibrosis and nucleus pulposus within an interior region defined by the annulus fibrosis, the method comprising:

removing at least a portion of the nucleus pulposus material from the interior region to define a space, wherein the step of removing the nucleus pulposus comprises creating an opening in the annulus fibrosis to access the interior region of the annulus fibrosis;

lining the space with a substantially nonporous liner material;

filling the space with a fill material sufficient to cause the liner material to expand to substantially engage tissue surrounding the space, the fill material comprising at least some of the nucleus removed from the disc; and

closing the opening after filling the space with fill material, wherein the closing step comprises applying energy to annular fibrosis tissue surrounding the opening.

28. The method of claim 27, wherein the fill material further comprises at least one of naturally occurring extra-cellular matrix material, saline, a pharmaceutical, an autologous therapeutic agent, a concentrated growth factor derived from centrifuged plasma of the patient, or genetic material.

29. The method of claim 27, wherein the step of lining the space comprises introducing a sheet of substantially nonporous, bioabsorbable material into the space.

30. The method of claim 27, further comprising introducing a flowable fill material into the interior region before introducing the lining the interior region.

31. The method of claim 30, wherein the flowable fill material comprises naturally occurring extra-cellular matrix material.

32. The method of claim 31, wherein the flowable fill material comprises a slurry further comprising at least one of saline, an antibiotic, a steroid, and an non-steroidal anti-inflammatory drug.

33. The method of claim 30, wherein the flowable fill material comprises an autologous therapeutic agent.